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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,238	05/08/2000	CORNELIA BERGHOF	2727-102	8813

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EXAMINER	
SOUAYA, JEHANNE E	
ART UNIT	PAPER NUMBER
1634	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/508,238	Berghof et al
Examiner	**Art Unit**
Jehanne Souaya	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 4, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *7, 8, 10, 12-14, 16, 17, 19, 20, and 22-44* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *7, 8, 10, 12-14, 16, 17, 19, 20, and 22-44* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

1. Claims 7, 8, 10, 12-14, 16-17, 19-20, 22-25, and newly added claims 26-44 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. Any rejections not reiterated are hereby withdrawn. The following rejections are either newly applied (necessitated by amendment) or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is FINAL.

2. The amendments have rendered the rejection under 35 USC 112/2nd paragraph, moot, therefore the rejection in section 4 of the previous office action is withdrawn.

3. The amendments have rendered the rejection under 35 USC 101, moot, therefore the rejection in section 8 of the previous office action is withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Maintained Rejections

Claim Rejections - 35 USC § 112

Written Description

5. With regard to claims 12-14, 16, and 17, the claims are dependent on a canceled claim, thus the claims are drawn to a method of detecting the presence or absence of any bacteria comprising using a kit and carrying out a nucleic acid hybridization or nucleic acid amplification

and detecting the presence or absence of bacterial belonging to a group of bacteria of the Pseudomonas species. These methods, broadly read on detecting any sequences from any pseudomonas species, including those that are unknown, which the specification does not teach or describe. Further, even if the claims were dependent on claim 26 or claim 30, for example, the following analysis being applied with regard to claims 7-8, 10, 19-20, 22-25, and newly added claims 26-44, the claims [claim 26, claim 30, etc] as written are drawn to a nucleic acid molecule comprising a nucleic acid sequence selected from the group consisting of SEQ ID NO 3-5 or the complements thereof, wherein the nucleic acid molecule "comprises" a shortened sequence as compared to that of SEQ ID NO 1. The recitation of "comprises" a shortened sequence encompasses a sequence of unlimited length that contains within it, a shortened sequence of SEQ ID NO 1 (which comprises SEQ ID NOS 3, 4, or 5, or the complements of such). This recitation encompasses the full intergenic spacer region of 23s-5s from any species of Pseudomonas, as well as to sequences larger than such up to full length genes from any source. Further, the recitation of 90% homologous in claim 42, or "10 contiguous nucleotides correspond to said nucleic acid in 9 out of 10 [or 8 out of 10] contiguous nucleotides" in claims 28, 29, 36, and 39, encompass sequences to the intergenic spacer region of any Pseudomonas species, including those that are unknown in the art, which have not been taught or described in specification. With regard to a nucleic acid which corresponds to SEQ ID NO 3 in 9 out of 19 contiguous nucleotides, for example, such a nucleic acid could differ from SEQ ID NO 3 in 11 out of 20 positions, thus encompassing a molecule which could read on a probe or primer for a

large number of other genes or sequences, from any species of Pseudomonas, which have not been described in the specification. The specification only teaches the nucleic acid sequence of a *region* of the 23s-5s [SEQ ID NO 1] intergenic spacer from Pseudomonas aeruginosa, as well as the nucleic acid sequences *consisting* of the sequences of SEQ ID NOS 3-5. The claimed sequences, however, read on the full intergenic spacer region of 23s-5s from any species of Pseudomonas, as well as to sequences larger than such up to full length genes from any source. With respect to claim 22, the claim reads on any sequence such that 20% of it's nucleotides can be modified in each string of 10 successive nucleotides. Such a claim would read on a sequence only having 60% complementarity to SEQ ID NO 3.

The claimed invention represents a broad genus for which a representative number of species of such a genus must be disclosed to fulfill the description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar,* 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date, applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the species of the isolated nucleic acids of SEQ ID NOS 1 and 3-5, or to methods of using such a broad genus of nucleotides, the specification fails to show that applicant was, in fact, "in possession of the claimed invention" at the time the application for patent was filed.

Response to Arguments

The response traverses the rejection. The response cites *In re Edwards*,568 F.2d 1349 (C.C.P.A. 1970) as the lead case on the written description requirement. The response further asserts that determining whether the written description requirement is satisfied requires reading the disclosure in light of the knowledge possessed by the skilled artisan. These arguments have been thoroughly reviewed but were found unpersuasive as the claims still encompass the full intergenic spacer region of 23s-5s from any species of Pseudomonas, as well as to sequences larger than such up to full length genes from any source, including probes or primers to such, which are not taught in the specification. It is further noted, that the claims are sufficiently broad as to encompass unknown sequences. With regard to the citation of *In re Edwards* these arguments have been thoroughly reviewed but were found unpersuasive. Firstly, the written description guidelines applied by the examiner are based on the *Regents of the University of California v. Eli Lilly* decision in 1997 which is directed to nucleic acids, whereas the CCPA decision in *In re Edwards* was in 1970. Secondly, the examiner has not required that the specification must outline each and every sequence encompassed by the claims, but a representative number of the species encompassed by the broadly claimed genus. The disclosed structural feature: an oligomer of SEQ ID NO 1 or oligomers within it, SEQ ID NOS 3-5, does not constitute a substantial portion of the claimed genus of sequences from any species, strain, or isolate of Pseudomonas, or the claimed genus of genes from any source. One of skill in the art, would not be able to envision the detailed chemical structure of the encompassed nucleic acid

molecules, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it, the polynucleotide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

For these reasons and the reasons made of record above, and in previous office actions, the rejection is maintained.

Claim Rejections - 35 USC § 103

6. Claims 7-8, 10, 12-14, 16-17, 19-20, 22-25, and newly added claims 26-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Accession number Y00432, March 18, 1991.

Accession number Y00432 teaches a nucleic acid molecule that contains 20 consecutive nucleotides that are identical to SEQ ID NO 2. Although Accession number Y00432 does not teach probes or primers or sequences containing modified oligonucleotides or detectable groups as stated in the claims, it would have been prima facie obvious to construct probes or primers to the known sequences, and to attach or include modified bases for the purposes of amplification and detection of such nucleic acids. Such methods were readily known and used in the art at the time the invention was made.

Response to Arguments

The response traverses the rejection. The response states that the fact that a claimed species or subgenus is allegedly encompassed by a prior art genus is not sufficient to establish a prima facie case of obviousness. This argument has been thoroughly reviewed but was found unpersuasive because in the present case, any small oligomer that consists of a sequence identical to a sequence within accession number Y00432 would be equivalent as a primer for the purpose of amplifying the sequence, absent evidence to the contrary. Given the sequence recited in Y00432, the ordinary artisan would have been able to generate a large number of oligomers that would have been equivalent as primers for the purpose of amplifying Y00432, including the sequence of SEQ ID NO 2. Designing a primer to amplify a known sequence was well within the skill of the ordinary artisan at the time the invention was made, as was including reporter groups for detection, and packaging such in kit format for the obvious improvement of providing preweighed, premeasured reagents to minimize experimental error.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

7. Claims 12-14, 16-17, 26-30, 31, 33, 34, 36,37, 39, 40, 42, and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 17 are indefinite as they are dependent on canceled claims.

Claims 26-30, 33, 36, 39, and 42 are indefinite in the recitation of "comprises" a shorter sequence than that of SEQ ID NO 1 as it is unclear whether the claim intends the nucleic acid molecule to be no longer than SEQ ID NO 1 (131 nucleotides), or if the claim intends that the nucleic acid molecule could encompass sequences that "comprise" a shorter sequence than SEQ ID NO 1, that is, that it could include an unlimited number of sequences on either side.

Claims 31, 34, 37, 40, and 43 are indefinite as it is unclear how the claims further limit the claim from which they depend. For example, claim 31 is dependent on claim 30. Claim 30 is indefinite because the scope of the recitation of "comprises" a shorter sequence than that of SEQ ID NO 1 is unclear. If claim 30 intends that the nucleic acid molecule is no longer than SEQ ID NO 1 (131 nucleotides), then claim 31 does not further limit the claim as it encompasses sequence of 132-250 nucleotides long.

Claim 42 is indefinite in the recitation of "allows the detection of ..." as it is unclear if the nucleic acid molecule detects Pseudomonas or whether the it is capable of such, but does not necessarily.

Claim Rejections - 35 USC § 102

8. Claims 30, 33, 36, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number X15400.

The claims as written encompass any nucleic acid molecule that contain 9 of 10 consecutive or 8 of 10 consecutive nucleotides from SEQ ID NOS 3-5 or is 90% homologous to SEQ ID NOS 3-5. Accession number X15400 teaches a sequence that possesses at least 10 consecutive sequences of SEQ ID NO 3.

Response to Arguments

The response traverses the rejection. The response asserts that the assertion of the office action that accession No. X15400 allegedly teaches a sequence that possesses at least 10 consecutive sequence of SEQ ID NO 3 is irrelevant because the DNA sequence encodes a zinc finger protein and does not enable the presently claimed invention. This argument has been thoroughly reviewed but was found unpersuasive because the intended use for the claimed sequences does not carry patentable weight with regard to 35 USC 102 or 35 USC 103. The only limitations in the claimed products are structural limitations which are anticipated by Accession number X15400.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. No claims are allowable.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1634
April 16, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600